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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,423	01/29/2000	Charles Christopher Negus	LE-199J	2221

7590

07/29/2003

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EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/29/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/493,423

Applicant(s)

Negus et al.

Examiner

Ahmed M. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 16, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 and 3 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,030,377. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because they are directed to analogous apparatus and methods of use for marking and delivering ablative energy to percutaneous myocardial revascularization channels in the heart wall.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1 and 3 are again rejected under 35 U.S.C. 102(e) as being anticipated by Linhares et al. U.S. Patent 6,030,377.

Linhares et al. disclose a percutaneous transmyocardial revascularizations catheter system **12** and method of use, the catheter system **12** comprising:

a treatment catheter **14** having a proximal end connected with a source of tissue ablative energy **24** and a distal tip for applying the ablative energy to the heart wall to create channels (see Fig. 1); and

a channel marking and drug delivery catheter [subsystem] **16** connected to a source of therapeutic or diagnostic agent (see Fig. 15), the catheter subsystem **16** having a distal end

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proximate the distal end of the treatment catheter **14** for applying an imaging and/or therapeutic agent in or proximate the channels.

5. Claims 1-3 are again rejected under 35 U.S.C. 102(e) as being anticipated by Swanson U.S. Patent 6,023,638.

Swanson discloses systems and methods for diagnosing and treating tissue, for example, percutaneous myocardial revascularization (Col. 42, lines 3-8), the systems comprising:

a treatment catheter **312** having a proximal end connected with a source of tissue ablative energy **378** and a distal tip for applying the ablative energy to the heart wall to create channels (see Figs. 38 and 39); and

channel marking and drug delivery catheter [subsystems] **314**, **316**, connected to an imaging medium source and a source of therapeutic or diagnostic agent for applying the imaging and/or therapeutic agent in or proximate the channel (Col. 13, lines 9-20) .

As to claim 2, the marking and drug delivery catheter subsystems of Swanson include at least two separate catheters **314** and **316** for applying the imaging medium and therapeutic or diagnostic agent in or proximate the channel (Fig. 39 and Col. 13, lines 11-12).

Response to Arguments

6. Applicant's arguments filed May 16, 2003 have been fully considered but they are not persuasive. The applicant makes the following arguments:

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A. The applicant argues that the channel marking and drug delivery catheter subsystem of the claimed invention “is in the form of two separate catheters.”

In response to this argument, although Fig. 12 of the present application depicts a catheter subsystem having two separate catheters, the applicant’s claims fail to positively recite a channel marking and drug delivery catheter subsystem in the form of two separate catheters. Hence, this argument lacks support in the claim language, and therefore is not considered.

B. As to the double patenting rejection of claims 1 and 3, the applicant argues that the catheter 16 of Linhares (U.S. Patent No. 6,023,638) “is not configured to deliver therapeutic or diagnostic agents and no therapeutic or diagnostic agents are disclosed in Linhares.” He further argues that the catheter subsystem of Linhares “is only a marking catheter connected only to dye syringe.”

In response to this argument, and as admitted by the applicant, the catheter subsystem 16 of Linhares, which is connected only to marking agent, delivers a marking agent such as an imaging dye to the treatment site so as to mark transmyocardial revascularization channels (see the abstract and Col. 4, line 16) . The recitation that the catheter of the present invention ‘is configured to deliver therapeutic or diagnostic agent’ is an intended use and has not structural limitation.

In this Office Action (OA), the marking agent of Linhares is treated as a marking and/or diagnostic agent. Therefore Linhares clearly provides marking/diagnostic agent to the treatment site as presently claimed. Furthermore, the catheter subsystem 16 of Linhares would also provide

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therapeutic agent to treatment site since there is not structural limitation that would prevent the delivery of the therapeutic agent.

C. As to U.S. Patent No. 6,023,638 to Swanson, although the applicant admits that the reference discloses 'operative elements including devices to deliver drugs or therapeutic material to body tissue,' he argues that "this is hardly a teaching under 35 USC 102."

In response to this argument, the Examiner maintains his position in the prior Office Action (refer to item # 5 above).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

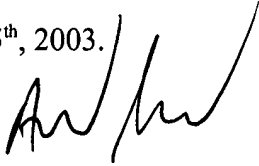
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; and the fax number for After Final is (703) 872-9303.

A. M. Farah

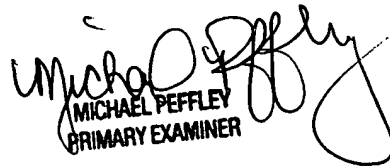
Patent Examiner (Art Unit 3739)

July 25th, 2003.



Linda C. M. Dvorak

Supervisory Patent Examiner



MICHAEL PEFFLEY
PRIMARY EXAMINER